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Customer No. 30223 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:	Atty. Docket No.: 47168-00035USC1
Richard J. Lazzara Thomas S. Heylmun Keith D. Beaty	Examiner: Paul Prebilic
	Group Art Unit: 3738
Application No.: 09/237,605	
Filed: January 25, 1999	
For: Infection-Blocking Dental Implant	

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DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action dated October 22, 2001, in the subject application, the declarant wishes to provide the following information supporting patentability of the invention claimed in the application.

1. I am Dr. Stephan S. Porter holding the degrees of M.S.D. from Indiana University School of Dentistry and of DDS and MS from the Ohio State University College of Dentistry. I have been employed by Implant Innovations, Inc. ("*3i*"), since July 1997, and currently hold the title of Senior Director of New Product Development and Research.

2. I am familiar with the pending claims, claims 11-50, that are directed to an implant having a certain type of surface. I am aware of the Office Action dated October 22, 2001, and the obviousness rejections in that Office Action. I understand that the analysis of the patentability of claims 11-50 should take into account certain facts related to the clinical success and the

commercial success of the claimed implant. I wish to provide evidence showing that dental implants having a roughened surface as claimed in the application have achieved substantial clinical efficacy. Furthermore, I wish to provide evidence showing that the implants having the claimed surface have been commercially successful, as evidenced not only by *3i*'s own sales figures, but also by competitors' marketing literature that suggests that even *3i*'s competitors have recognized the commercial success of the claimed implants.

3. Dental implants having a roughened surface according to the invention have been designated to have an Osseotite® surface by *3i*, the assignee of the present application. Attached as Exhibit "A" is a surface map of the Osseotite® surface made by an interferometric microscope. The threaded implant is made of titanium and has been prepared in accordance with a two-step, acid-etch treatment wherein the native oxide layer is substantially removed via hydrofluoric acid and the resultant surface is etched with a combination of sulfuric and hydrochloric acids. The resulting topography has a substantially uniform array of substantially cone-shaped irregularities with peak-to-valley heights of less than 10 microns. I have personally placed and restored numerous implants, including *3i*'s Osseotite® implants.

4. Implants with an Osseotite® surface, like that shown in Exhibit "A," have been marketed by *3i* since 1996. Sales of implants with the Osseotite® surface have rapidly increased relative to *3i*'s implants with other types of surfaces since 1996. In 2001, implants with the Osseotite® surface accounted for 94% of all implants sold by *3i*, as shown in the table below.

U.S. Sales Year	% Implants Sold Having Osseotite® Surface	% Implants Sold Without Osseotite® Surface
1996	17	83
1997[1]	30-40	60-70
1998	58	42
1999	87	13
2000	90	10
2001	94	6

5. Implants having different types of surfaces other than an Osseotite® surface were offered for sale at the same time, as shown by *3i*'s 1997 Surgical Catalog, 1998, 2000, 2001, and 2002 Price Lists, and 2000 Surgical Catalog, all of which are attached as Exhibit "B." Threaded implants with machined titanium surfaces and cylindrical implants having plasma sprayed titanium surfaces (TPS) were also available. Generally, where *3i* offers for sale an implant with the Osseotite® surface, a threaded implant of the same size with a machined surface is offered, and also a cylindrical implant with a TPS surface may be offered. See, e.g., Exhibit "B," 2000 Surgical Catalog, pp. 4, 5, 8, 9, 12, 13, 16, 17, 22, 23, 28 and 29. When comparing the machined surface implants and the TPS implants with the Osseotite® surface, the difference between the implants is related to the surface in contact with bone. It can be concluded that dental clinicians prefer to use the Osseotite® surface rather than the machined surface or the TPS surface. In each size, implants having an Osseotite® surface are more expensive than the threaded implants with the machined surface and the cylindrical implants having the TPS surface, as shown in the Price Lists (Exhibit B). Thus, the commercial success of the Osseotite® surface cannot be attributed to a cost advantage.

[1]Estimates based on actual number sold between July and December 1997.

6. The success of implants having an Osseotite® surface is related to the superior osseointegration that it achieves. After being installed, implants must be allowed to integrate with the adjacent bone in order that forces which will be imposed by an artificial tooth installed on the implant can be transferred to the bone. Failure to achieve osseointegration means that the implant loosens and must be removed. Traditionally, the period required for osseointegration had been three to six months after installation of the implant, depending on the location where the implant is installed. In 1999, after clinical experience and experimental evidence showed that the time required for functional osseointegration was significantly reduced for implants having Osseotite® surfaces, ***3i*** began recommending that its Osseotite® implants could be loaded with the final prosthesis after only two months of osseointegration, regardless of the location at which the implant is placed. The United States Food and Drug Administration approved of ***3i***'s marketing of the Osseotite® implants in this manner and a copy of ***3i***'s FDA submittal is enclosed as Exhibit C. As will be seen in the clinical tests reported in Exhibit C, the Osseotite® surface was found to have a particularly suitable roughness for migration of osteogenic cells needed for osseointegration of bone with the titanium surface of the implant.

7. As can be seen in the table in paragraph 4 above, sales of ***3i***'s implants having Osseotite® surfaces increased from 58% in 1998 to 84% in 1999 relative to all implants sold. I attribute this commercial success of the Osseotite® surface to the fact that the clinically-proven enhanced osseointegration achieved by the Osseotite® surface satisfied a long-felt need in that clinicians (as well as patients) would much prefer to reduce the time during which the patient lacks the final prosthesis. Thus, the Osseotite® surface has made possible an important advancement in the art of implantology, as has been recognized by patients, dentists, and ***3i***'s own competitors.

8. From the mid-1980's until 1996, when ***3i*** introduced its Osseotite® surface, the vast majority of implants that were sold to clinicians in the United States had either a machined surface, a TPS surface, or an HA (hydroxy apatite) surface. In recent years, the commercial success of ***3i***'s Osseotite® surface has been recognized by competitors. Exhibit "D" includes marketing literature in which a competitor is marketing an implant that has a roughened surface (not TPS or HA, both of which are roughened surfaces) that is compared with the Osseotite® surface of ***3i***. This competitive literature is dated between 1998 and 2001, after the clinical success of ***3i***'s Osseotite® surface had become well-documented. In the first piece of literature, dated 2000, Steri-Oss, a Nobel Biocare subsidiary, is comparing its acid-etched surface to ***3i***'s Osseotite® surface. In the second piece of literature, Nobel Biocare's commercial journal entitled "Applied Osseointegration Research Journal" dated October 2000, Nobel Biocare compares its TiUnite™ surface with ***3i***'s Osseotite® surface at pp. 25-30. In the third piece of literature, dated 1998, ITI Straumann compares its SLA surface (which was apparently to be commercially released in the United States in late 1998) with ***3i***'s Osseotite® surface. In the fourth piece of literature, dated 2001, LifeCore Biomedical compares its RBM™ surface with ***3i***'s Osseotite® surface and Straumann's SLA surface. As these companies represent the world's largest dental implant manufacturers that sell implants in the United States, it is evident that competitors consider the Osseotite® surface to be the "Gold Standard" to which they compare their own roughened surfaces. Competitive flattery via these product comparisons is compelling evidence of the commercial success of ***3i***'s Osseotite® surface.

9. The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this

Declaration, declares that the facts set forth in this Declaration are true, and all statements made of his own knowledge are true, and all statements made on information and belief are believed to be true.

Date: 4/18/02

Stephan S. Porter